

REMARKS

After entry of this amendment, claims 11-17, 19-21, 23, 25, and 27-29 are pending. The claims have been amended without prejudice or disclaimer. Support for the amendments is found *inter alia* in the original claims. The amendments to claims 11 and 17 find further support in the specification at page 3 and at page 10, lines 34-41. New claims 30 and 31 find further support in the specification at page 10, lines 37-41. No new matter has been added.

Rejections under 35 U.S.C. § 103

Claims 11-17, 19-21, 23, 25, and 27-29 are rejected as being obvious under 35 U.S.C. § 103(a) over Barendse *et al.* (U.S. Patent No. 6,500,426, hereinafter “Barendse”) in view of Jacobsen *et al.* (U.S. Patent No. 5,391,371; “Jacobsen”) and Millar *et al.* (U.S. Patent No. 2,991,226; “Millar”). Applicants respectfully disagree and traverse the rejection.

The examiner bears the initial burden of establishing *prima facie* obviousness. See *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). To support a *prima facie* conclusion of obviousness, the prior art must disclose or suggest all the limitations of the claimed invention. See *In re Lowry*, 32 F.3d 1579, 1582, 32 USPQ2d 1031, 1034 (Fed. Cir. 1994).

The Examiner relies on Barendse for allegedly teaching pelleted enzyme-containing granules. The Examiner also contends that Barendse teaches that the granulate can be coated, prior to pelleting, to improve the stability of the enzyme to the environment and that such coating can comprise fat, wax, polymer, salt or ointment, referring to col. 5, lines 58-68. Contrary to the Examiner’s assertion at col. 5, lines 58-68, Barendse does not teach that this general disclosure of coating is applied “prior to pelleting.” Barendse does not mention anything about pelleting in this general disclosure of coating.

Further, there is no disclosure of any specific polymer for coating of granules, rather the polymers described in Barendse must be *incorporated* into the granules. Barendse does not teach or suggest that *coating* provides greater pelleting stability than an uncoated granulate as required by the claims. To the contrary, Examples 6 and 7 describe the use of cellulose-based polymers HPMC or HEC as a carrier matrix which is *mixed* with the core carbohydrate material

to provide a pelleting-stabilized formula. Barendse describes their invention as filling the “need for stable formulations of enzymes that are based on a carrier that is suitable for granulation methods other than pelleting and that can have a high absorption capacity.” (see Barendse at col. 2, lines 28-31; emphasis added). Thus Barendse deals with a completely different problem and method than those of the present application.

The Examiner acknowledges that Barendse does not teach a granulate coated with the claimed polymer (see Office Action at page 4), and relies on Jacobsen for allegedly teaching coating of enzyme-containing fodder components to protect from heat during pelleting. Applicants strongly disagree with the Examiner’s characterization of Jacobsen. Jacobsen does not teach or suggest that the pelleting stability may be obtained by merely applying a polymer coating. To the contrary, Jacobsen discloses that a very specific combination of (a) a specific carrier, *i.e.* the ***T-granulate*** containing 2-40% of finely divided cellulose fibers, and (b) a coating based on ***high-melting fat or high-melting wax***, is necessary to obtain the pelleting stability disclosed. Jacobsen further stresses the importance of this particular combination disclosing that coating with fat or wax alone was not sufficient for stabilizing enzymes during the pelleting process (see Jacobsen col. 2, lines 22 to 50). Jacobsen also discloses that it was surprising that the use of the T-granulate gave rise to a stable fodder. Thus, Jacobsen teaches that a very specialized support material, the T-granulate, with a coating of fat or wax are essential for obtaining pelleting stability.

The Examiner alleges that Jacobsen teaches that T-granulates have been traditionally coated with PEG at col. 1, lines 44-46. From this assertion the Examiner concluded that Jacobson allegedly teaches that the pelleting stability of enzyme-containing granules is increased by coating the granule with a high melting wax or fat or PEG (see Office Action at page 5, lines 11-12). The Examiner also contends that Jacobsen teaches that coating with PEG is able to achieve increased pelleting stability (Office Action at page 5, last sentence). These characterizations are contrary to the disclosure of Jacobsen. The Examiner has taken the mention of PEG out of context and has not considered the teaching of the reference as a whole, as required. Rather the only reference to PEG in Jacobsen is at col. 2 line 46 and relates to T-granulates which had been used as additives to detergents (see col. 2, lines 36-50). Contrary to

the Examiner assertion, nowhere in Jacobsen is there any disclosure of PEG being used or having been used as a coating for feed granules or having any association with pelleting or pelleting stability. Jacobsen teaches that for improved pelleting stability, the very specific combination of the T-granulate and the coating of fat or wax are essential.

The Examiner relies of Millar for allegedly teaching PEG having a molecular weight of 1500-6000. Applicants respectfully submit that Millar is not relevant. Millar relates to preparation of a penicillin tablet having a specific release profile. Millar describes a specific tablet for the pharmaceutical drug penicillin with various layers to prolong the release of penicillin in the intestinal tract. There is no disclosure of enzymes in Millar. The PEG disclosed in Millar is used as a barrier layer and is applied *after* tableting and compressing of the penicillin containing core (see Millar col. 3, lines 4-12). Millar does not disclose that the tablets contain any enzymes or address any problems associated with pelleting stability, *i.e.* stability against the thermal stress associated with preparation of pelletized feed stuffs.

Neither Barendse, Jacobsen, nor Millar alone or in combination teach or suggest the method of present claim 1: a method for preparing a pelletized feedstuff composition, which comprises pelletizing a mixture of animal feed constituents and an enzyme-containing granulate suitable for use in animal feed, the enzyme-containing granulate comprising a mixture of at least one enzyme and a solid support suitable for feedstuffs wherein the solid support is a low-molecular-weight inorganic or organic compound selected from inorganic salts or sugars, wherein the granulate is coated with an organic polymer which is suitable for feedstuffs selected from the recited group of polymers, and wherein the granulate has a pelleting stability greater than an uncoated granulate. Because all the claim limitations are not taught or suggested by the references cited by the Examiner, a *prima facie* case of obviousness has not been established.

Additionally, it is well established that under 35 U.S.C. § 103 the Examiner must consider the reference in its entirety, *i.e.* as a whole, including portions that teach away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984); see also *KSR*, 127 S. Ct. at 1740; MPEP § 2141.03 (VI). It is improper to combine references where the references teach away from their

combination. *See* MPEP § 2145 (X)(D)(2) (citing *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983)).

Barendse is not combinable with Jacobsen and/or Millar for the following reasons. Barendse addresses improving pelleting stability of granules by **incorporating** compounds which is a totally different process than **coating**. As explained above, Barendse does not teach or suggest that **coating** provides greater pelleting stability than an uncoated granulate as required by the present claims. To the contrary, Examples 6 and 7 describe the use of cellulose-based polymers HPMC or HEC as a carrier matrix which is **mixed** with the core carbohydrate material to provide a pelleting-stabilized formula. Further, in Example 9, Barendse demonstrates improved stability because of the granulates made using a carbohydrate carrier (see col. 11, lines 64-67 and col. 12 Table 1). Barendse does not disclose that any additional measures would be required for obtaining pelleting stability. Barendse rather discloses that “[f]urther improvement of pelleting stability could be obtained where desirable by the **incorporation** of hydrophobic, gel-forming-or-slow dissolving . . . compounds.” (Barendse at col. 6, lines 38-41; emphasis added). Barendse further recites “[i]n other embodiments additional ingredients can be **incorporated** into the granulate where desirable, e.g., as processing aids, for further improvement of the pelleting stability and/or the storage stability of the granulate.” (Barendse col. 6, lines 8-12; emphasis added). Thus, Barendse teaches improving pelleting stability by **incorporating** ingredients **into** the granulate rather than coating **onto** the granulate. One of skill in the art would not look to any reference regarding coating of granulates for improved pelleting stability as allegedly taught by Jacobsen based on a teaching of **incorporating** ingredients for increasing stability as taught by Barendse. Consequently, Barendse is not combinable with Jacobsen.

In addition, Jacobsen is not combinable with Barendse or Millar. As explained above, Jacobsen teaches that coating with fat or wax was not sufficient for stabilizing the enzyme during the pelleting process. Jacobsen teaches that for improved pelleting stability, the very specific combination of the T-granulate and the coating of fat or wax are essential. Because this particular combination is essential for obtaining improved pelleting stability, the T-granulate and/or the coatings cannot be substituted. Jacobsen therefore teaches away from a combination with Barendse which uses a different type of granulate requiring **incorporating** ingredients for

achieving pelleting stability. Because Jacobsen requires a specific combination with use of a particular granulate, *i.e.* the so-called T-granulate, one of skill in the art would not look to a reference with a different type of granulate requiring *incorporating* ingredients for pelleting stability. Consequently, Jacobsen is not combinable with Barendse.

Moreover, a reasonable expectation of success must be established for a proposed combination of references to render claims *prima facie* obvious. See MPEP § 2143.02 (citing *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986)). Assuming *arguendo* Barendse and Jacobsen were combinable, there would be no expectation of success since Barendse teaches improved pelleting stability by *incorporating* ingredients into the granulate not by coating. Further because Jacobsen teaches that the T-granulate is essential with the wax or fat coating for improved pelleting stability, there would be no expectation of success for substituting essential elements.

The Examiner relies on the mention of PEG in Jacobsen for the combination with Millar. As explained above, Jacobsen does not disclose PEG for coating of feed granules or as having any association with pelleting or pelleting stability, contrary to the Examiner's assertions. Because Jacobsen does not teach coating granulates with PEG for improved pelleting stability, disclosure of certain molecular weights of PEG in Millar is not relevant. Further, Millar describes a specific tablet for the pharmaceutical drug penicillin with various layers to prolong the release of penicillin in the intestinal tract, with one or more barrier layers comprising PEG which are applied *after* tableting. There is no disclosure of enzymes in Millar. Millar does not disclose stabilizing the activity of penicillin but rather of using the various layers on the tablet for timing the release of penicillin in the stomach and the intestine. There is no disclosure of substitutions for penicillin or of pelleting stability, *i.e.* stability against the thermal stress associated with preparation of pelletized feed stuffs. One skilled in the art would not look to a reference regarding timing of release of a drug from a tablet with layers dissolvable in the intestinal track as taught by Millar for stability against the thermal stress associated with preparation of pelletized feed stuffs. Assuming *arguendo* Barendse, Jacobsen and Millar were combinable, there would be no expectation of success since Millar teaches barriers layers for providing various dissolution times in the acidic environment of the stomach or in the intestine

and not as giving stability relating to heat stress during the pelletizing process. Consequently, Millar is not relevant and is not combinable with Jacobsen and/or Barendse. Accordingly, the Examiner has not established a *prima facie* case of obviousness for this additional reason.

Reconsideration and withdrawal of the obviousness rejection is respectfully requested.

Claims 11-17, 19-21, 23, 25, and 27-29 are rejected as being obvious under 35 U.S.C. § 103(a) over Barendse in view of Jacobsen and Millar in further view of Good *et al.* (U.S. 4,689,297; "Good"). Applicants respectfully disagree and traverse the rejection.

The explanations provided above for Barendse, Jacobsen and Millar are equally applicable to this rejection and are incorporated herein in their entirety. The Examiner relies on Good for allegedly teaching a method of preparing pelletized enzyme-containing particles by coating a hydratable core-particle with an enzyme and then a film-forming macromolecular material asserting that the preamble of claim 11 is allegedly met because a particle that contains an enzyme is found. The Examiner concludes that it would be obvious to use any of the polymers disclosed by Good because they allegedly have the same purpose to stabilize an enzyme-containing granulate (Office Action at page 7, lines 14-16) and are equivalent alternatives (Office Action at page 8). Applicants strongly disagree with this characterization. The preamble of claim 11 recites a method for preparing a pelletized feedstuff composition. There is no disclosure of feedstuff in Good. Good rather describes a method for making dry and dust free enzyme granulates for use in laundry detergents. As explained in the Amendment and Reply Under 37 CFR § 1.111 dated March 31, 2008, the only disclosure in Good referring to a pelletized granule is "bentonite/kaolin/diatomaceous earth disk pelletized granules" as an example of a possible core particle which is subsequently coated with an enzyme (see col. 3, lines 13-20) and which can be *subsequently* coated with a film-forming macromolecular material. In contrast, claim 11 recites that the method comprises pelletizing a mixture of feed constituents and an enzyme-containing granulate suitable for use in animal feed which comprises a mixture of at least one enzyme and a solid support suitable for feedstuffs. Thus the pelletizing of the instant claims is conducted with a granulate already containing an enzyme and a coating

before the pelletizing step, in contrast to Good where the enzyme and the film-forming macromolecular material are *subsequently* coated onto a core or pellet. Good does not disclose that the polymers can be used for the purpose of stabilizing an enzyme-containing granulate, contrary to the Examiner's assertion, since both the enzyme and the polymers are applied to provide dust free granules for detergents and are applied *after* any pelletizing step.

Assuming *arguendo* Good was combinable with Barendse, Jacobsen and/or Millar, there would be no expectation of success because the film-forming macromolecular material and even the enzymes taught by Good are not applied before pelletizing. Good does not disclose pelletizing a mixture comprising a granulate already containing an enzyme or that the particles could withstand temperatures during a pelletizing step (see Amendment and Reply Under 37 CFR § 1.111 dated March 31, 2008, at page 8-9).

Good does not remedy the deficiencies of Barendse which does not teach or suggest coating an enzyme-containing granulate for improved pelleting stability. Good does not remedy the deficiencies of Jacobsen that requires a specific combination of a T-granulate and a wax or fat coating and which does not teach PEG as a coating for feed granules or as improving pelleting stability. Good also does not remedy the deficiencies of Millar which teaches a tablet for penicillin with layers applied to a core or an already tableted core, *i.e.* not prior to pelleting as required by the claims. Thus Barendse, Jacobsen, Millar and Good, alone or in combination, do not render the claims obvious.

Because the references cited by the Examiner, alone or in combination, do not teach all the claim limitations, because they teach away from their combination, and because assuming *arguendo* they were combinable there is no expectation of success, a *prima facie* case of obviousness has not been established. *See In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988) (holding that if an independent claim is nonobvious then any claim dependent therefrom is nonobvious). Reconsideration and withdrawal of the rejection is respectfully requested.

Double Patenting

Claims 11-17, 19-21, 23, 25, and 27-29 are rejected on the ground of nonstatutory obviousness-type double-patenting over Barendse in view of Jacobsen and Millar in further view of Good. Applicants respectfully disagree and traverse the rejection.

The Examiner rejects the claims based on the same arguments as presented above under the § 103 rejection. The explanations provided above for Barendse, Jacobsen, Millar, and Good are equally applicable to this rejection and are incorporated herein in their entirety. The Examiner further summarizes the rejection stating that Barendse teaches all the claimed elements except coating granules with the claimed polymers. Applicants disagree. Barendse teaches that the pelleting stability and any improvements on pelleting stability relate to the *incorporation* of ingredients into the granulates.

The Examiner further alleges that Jacobsen support coating enzyme containing granules with PEG to improve stability to the pelleting process. Applicants strongly disagree with the Examiner's characterization. Nowhere in Jacobsen is there a disclosure of PEG being used to improve pelleting stability. As explained above, the only disclosure of PEG relates to coating detergent granules. Jacobsen does not disclose PEG for coating of feed granules or as having any association with pelleting or pelleting stability. Contrary to the Examiner's assertion, Jacobsen discloses that for improving pelleting stability the particular combination of a T-granulate and a coating of wax or fat is essential and thus not substitutable.

The Examiner also contends that Millar and Good disclose polymers for coating enzyme-containing granules or sensitive pharmaceutical substances. Applicants strongly disagree with the Examiner's characterizations. The coatings applied to the granules disclosed in Millar and in Good are not applied before a pelletizing step, thus no expectation of success is provided that these coating could improve pelleting stability. Further, the barrier layer of Millar is applied in order to allow time release of penicillin in the intestinal tract, thus the barrier layers provide protection against the acid in the stomach which is unrelated to providing protection from *heat* during the pelleting process of a granulate for use in animal feed. Further, the coatings in Good as with the enzyme in Good are applied to a core or already pelleted core. The only disclosure in

Good referring to a pelletized granule relates to an example of a possible core which is *subsequently* coated with an enzyme and can be coated with a film-forming macromolecular material for obtaining a dust free enzyme containing particle for use in laundry detergent.

As explained in more detail above under the § 103 rejection, because the references cited by the Examiner, alone or in combination, do not teach all the claim limitations, because they teach away from their combination, and because assuming *arguendo* they were combinable there is no expectation of success, a *prima facie* case of obviousness has not been established. Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1 and 13 are provisionally rejected on the ground of nonstatutory obviousness-type double-patenting over claim 17 of co-pending Application No. 10/280,324 (hereinafter “the 324 application”) in view of Jacobsen and Millar in further view of Good. Applicants respectfully disagree and traverse the rejection.

The ‘324 application is a continuation of Barendse discussed above and as such the specification of the ‘324 application is identical to that of Barendse. Thus the explanations above relating to Barendse would correspond to the ‘324 application. The explanations provided above for Barendse, Jacobsen, Millar, and Good are equally applicable to this rejection and are incorporated herein in their entirety.

The Examiner alleges that it would be obvious to coat the granule of the ‘324 application with any polymer disclosed by Good prior to combination with feedstuff and pelleting. The Examiner further alleges that the polymers taught by Good have the same purpose to stabilize enzyme-containing granulates. The Examiner also contends that there would be a reasonable expectation that the polymers taught by Good would increase pelleting stability because Jacobsen allegedly teaches that coating with PEG is able to achieve this purpose. Applicants strongly disagree with the Examiner’s characterizations and conclusions.

As explained above for Barendse, the ‘324 application addresses improving pelleting stability of granules by *incorporating* compounds which is a totally different process than the

coating of the present invention. The '324 application discloses that any improvements on pelleting stability relate to the *incorporation* of ingredients into the granulates as explained above for Barendse. The '324 application also does not teach or suggest that *coating* provides greater pelleting stability than an uncoated granulate as required by the present claims.

The Examiner bases the use of the polymers of Good with the granule of the '324 application on the alleged disclosure of Jacobsen related to PEG. As explained above, nowhere in Jacobsen is there a disclosure of PEG being used to improve pelleting stability. As explained above, the only disclosure of PEG in Jacobsen relates to coating detergent granules. Jacobsen does not disclose PEG for coating of feed granules or as having any association with pelleting or pelleting stability. Contrary to the Examiner's assertion, Jacobsen discloses that for improving pelleting stability the particular combination of a T-granulate and a coating of wax or fat is essential and thus not substitutable.

Furthermore there would be no reasonable expectation of success because Jacobsen does not teach or disclose that PEG relates to pelleting stability, contrary to the Examiner's assertion. Further, the polymers disclosed in Good were applied to the core or pellet *subsequently* to any possible pelleting. The only disclosure in Good referring to a pelletized granule relates to an example of a possible core which is *subsequently* coated with an enzyme and can be coated with a film-forming macromolecular material for obtaining a dust free particle for use in laundry detergent. Because the coatings and/or granulates in Jacobsen are not substitutable as explained above, the polymers of Good are not equivalent alternatives and would not be expected to achieve the same results as alleged by the Examiner.


As explained in more detail above under the § 103 rejection, because the references cited by the Examiner, alone or in combination, do not teach all the claim limitations, because they teach away from their combination, and because assuming *arguendo* they were combinable there is no expectation of success, a *prima facie* case of obviousness has not been established. Reconsideration and withdrawal of the rejection is respectfully requested.

CONCLUSION

In view of the above amendments and remarks, Applicants believe the pending application is in condition for allowance. If any outstanding issues remain, the Examiner is invited to telephone the undersigned at the number given below.

Accompanying this response is a petition for a one-month extension of time, to and including November 11, 2008 to respond to the Office Action mailed July 11, 2008 with the required fee authorization. No further fee is believed due. However, if an additional fee is due, the Director is authorized to charge our Deposit Account No. 03-2775, under Order No. 13111-00039-US from which the undersigned is authorized to draw.

Respectfully submitted,

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